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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,824	02/08/2006	Marcello Allegretti	3765-0115PUS1	8576

2292 7590 07/03/2008  
BIRCH STEWART KOLASCH & BIRCH  
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FALLS CHURCH, VA 22040-0747

EXAMINER
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LOEWE, SUN JAE Y

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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07/03/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,824	<b>Applicant(s)</b> ALLEGRETTI ET AL.	
	<b>Examiner</b> SUN JAE Y. LOEWE	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 1-3, 4-6 and 8 are pending in the instant application. Claim 4 remains withdrawn as being drawn to non-elected subject matter.

#### *Response to Amendment/Arguments*

2. Applicant's response and claim amendments have been fully considered. The grounds of objection/rejection set forth in the office action dated November 1, 2007 are maintained and hereby made FINAL. Responses to arguments are provided below.

3. The generic claims remain rejected and prosecution is currently limited to the elected species of ~~“(R)-(-)-3-[(4'-isobutyloxyphenyl)]butan-2-one.~~. Compounds of Formula I that are not the elected species remain withdrawn from further consideration. Applicant is entitled to rejoinder of non-elected species upon allowability of the generic claims.

#### *Claim Objections*

4. Claims 1-3, 5, 6 and 8 remain objected to for containing non-elected subject matter. Due to non-allowability of the generic claims, the elected subject matter is currently limited to the elected species. Other claimed compounds within Group I (~~process of using products of Formula I wherein Ar=phenyl and R<sup>A</sup>/R<sup>B</sup>=H, unsubstituted alkyl, or alkyl substituted with peroxide~~; restriction requirement dated July 31, 2007) remain withdrawn as being non-elected subject matter.

***Claim Rejections - 35 USC § 112***

5. Below are responses to Applicant's remarks:

- a) “It would appear that the Examiner’s analysis hinges on the fact that not all of the compounds have been reduced to practice. But reduction to practice is not required.”

Applicant’s response is noted, however, it is not found to be persuasive. The analysis does not hinge on the fact that all compounds have not been reduced to practice. Rather, the disclosure of species within the claimed genus appears to be limited to the compounds reduced to practice. If this is incorrect, and the specification does have disclosure of species in addition to those reduced to practice, Applicant is encouraged to provide such showing.

- b) “The fact that experimentation is required is not problematic and the *In re Wands* court has stated that even a considerable amount of experimentation is permissible if the experimentation is routine. Here, Applicants are using standard and well known screening techniques reported in the scientific literature. Thus, such experimentation as is required to test additional compounds within the scope of the claims for activity is routine, and not “undue.”

MPEP 2164.03

The scope of the required enablement varies

inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaack*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

It is maintained that the predictability in the instant field of endeavor is low; evidence indicates that one of ordinary skill could not predict the operability of the invention of any species other than those disclosed. The species disclosed do not adequately represent the claimed genus.

c) “The Specification

states that psoriasis, rheumatoid arthritis, ulcerative colitis, acute respiratory distress syndrome (ARDS), idiopathic fibrosis, glomerulonephritis and bullous pemphigo are correlated with IL-8 inhibition (see the references cited on page 9, line 29 to page 10, line 8). For example, inhibition of IL-8 is suggested as a treatment for rheumatoid arthritis by Seitz *et al.* (see page 468) and has also been recognized by the EPO (see European Patent EP0894591). Page 1898 in Nickoleff *et al.* states "in the present study, the IL-8 gene expression by alveolar macrophages from the IPF and IPF-CTD patients studied appears to be specifically related to disease and not to some other exogenous stimulus." In addition, inhibition of IL-8 as a model for treatment of ulcerative colitis has been recognized by the USPTO (see US 5,707,622); inhibition of IL-8 is also recognized as a model for prevention of ARDS (see Mukaida *et al.* (1998) *Inflammation Research* 47:151-157); inhibition of IL-8 is further recognized by the USPTO as treatment for glomerulonephritis (see US 5,707,621) and IL-8 inhibition is recognized as the mechanism of action for treatment of bullous pemphigoid by dapsone (see Schmidt *et al.* (2001) *Clin Exp Immunol* 124:157-163. Consequently, the teachings in the instant application do, indeed, present the correlation between IL-8 and the claimed disease treatments.

Applicant's arguments are noted, however, they are not persuasive for the following reasons. The instant claims are drawn to nascent technology, ie. the method of treating diseases using compounds of Formula I. MPEP 2164.03 provides

("Nascent technology, however, must be enabled with a 'specific and useful teaching.' The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology."

Moreover, the art of using IL-8 inhibition for treating the claimed diseases appears to be unpredictable (Section 8b, office action dated November 1, 2007). Therefore, it is maintained that the analysis of the Wands factors provided in the previous office action is still proper.

The 35 USC 112 1<sup>st</sup> paragraph rejection is maintained and hereby made FINAL. Claims 1-3, 5, 6 and 8 remain rejected.

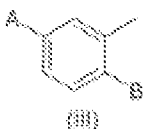
### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's cancellation of "~~which represents a residue of formula III~~" makes it unclear whether



represents an alternative for "Aryl" or for a "substituent to Aryl." Appropriate correction is requested.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./  
6-23-2008

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626